REMARKS

The Examiner is thanked for the due consideration given the application. This amendment is being filed concurrent with a Request for Continued Examination.

Claims 2-10 and 13-23 are pending in the application. New independent claims 16 and 17 are presented for consideration on the merits. New claims 18-23 set forth the allowable subject matter acknowledged by the Office Action.

No new matter is believed to be added to the application by this amendment.

The Drawings

The drawings have been objected to as not showing very feature of the present invention specified in the claims, i.e., the "lost motion connection."

However, in the previous response an explanatory statement was appended to the end paragraph beginning on page 6 line 19 to state "There is thus a lost-motion connector between knob 5 and ring 8". The connection is therefore illustrated in Figure 1 and more particularly in Figures 4a to 4d, which show in Figures 4a and 4b rotation being transmitted from the knob 5, via the grooved shaft 14 and the splines 17 to the hub 15 to the peg 20 on the end of the resilient arm 19. The peg pushes on one of the teeth 8 on the ring 7. However, when peg 20 reaches an angular position a few degrees clockwise from that shown in

Figure 4(c) it is cammed out of engagement by the surface 13 on the ring 9, so that further motion is lost. The lost motion connector therefore may be seen as comprising the indexer 16 and the ring 9. In the linear embodiment of Figures 5 to 10, the lost motion converter includes the stud 37 and the grooves 32 (see Figure 9).

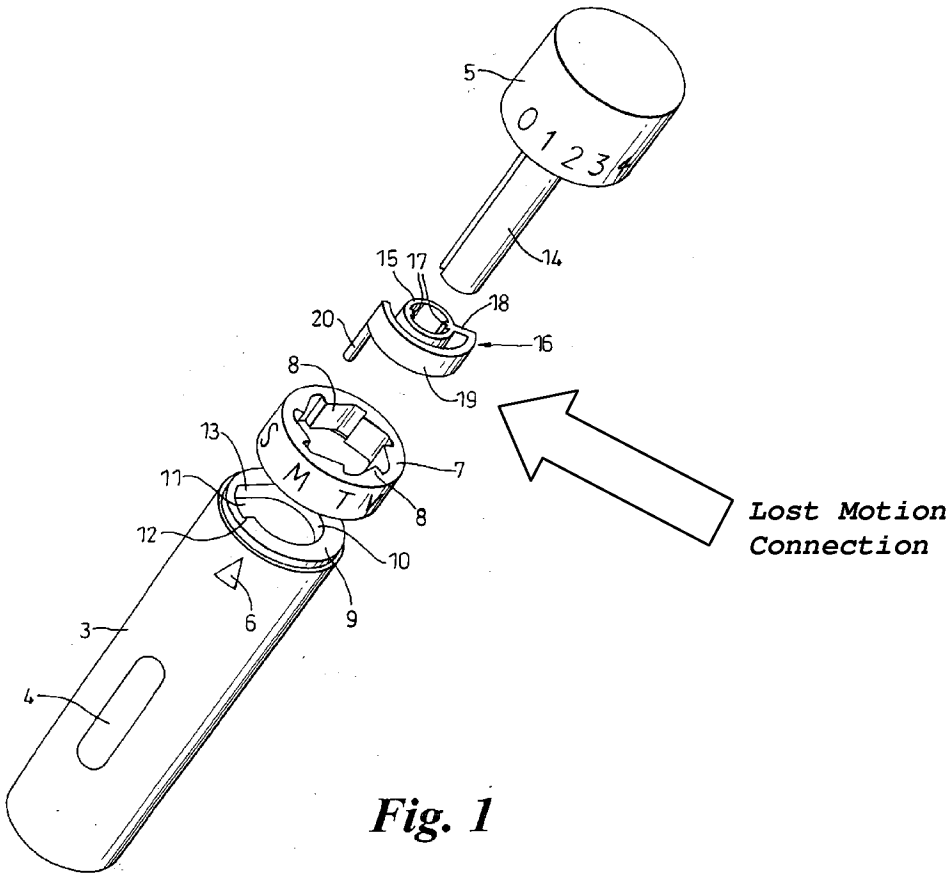


Fig. 1

Also, a search through the USPTO database for the same family shows that there are 1213 U.S. patents containing the phrase “lost motion connection” in the claims.

Withdrawal of this objection to the drawings is accordingly respectfully requested.

Rejection Over BALKWILL

Claims 2-10 and 13-15 have been rejected under 35 USC §102(b) as being anticipated by BALKWILL (U.S. Patent 5,279,585). This rejection is respectfully traversed.

In the conventional art, it is very common to have counter dials or index marks to allow a user to dial in a dose of a required volume. But it is unique so far as the applicant is aware to provide an arrangement which receives/responds to the motion applied to the dose setting element, whether that dose setting motion be angular (embodiment of Figures 1 and 4) or linear (embodiment of Figures 6 to 10). Figure 1 has been reproduced above. Figures 4 and 10 are reproduced below.

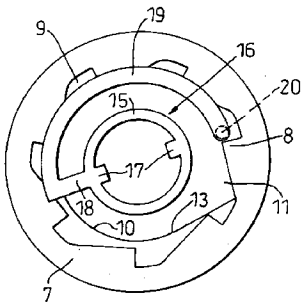


Fig. 4a

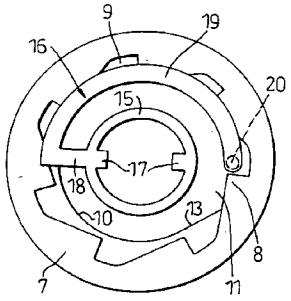


Fig. 4b

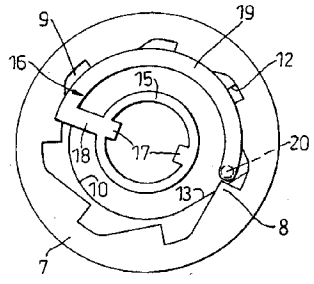


Fig. 4c

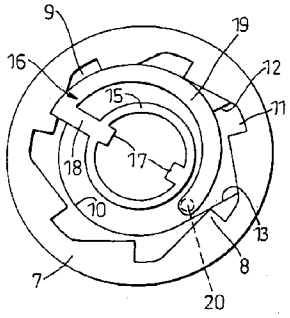


Fig. 4d

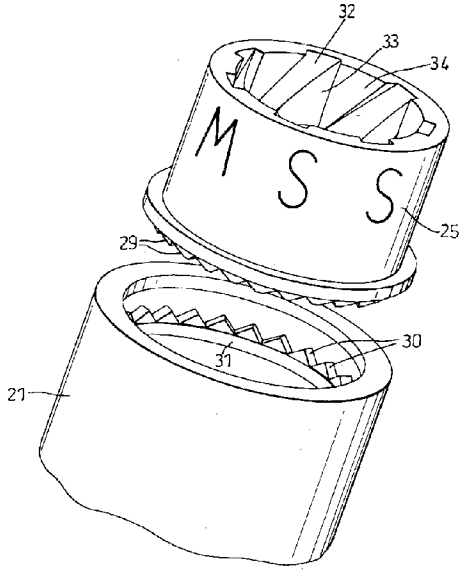


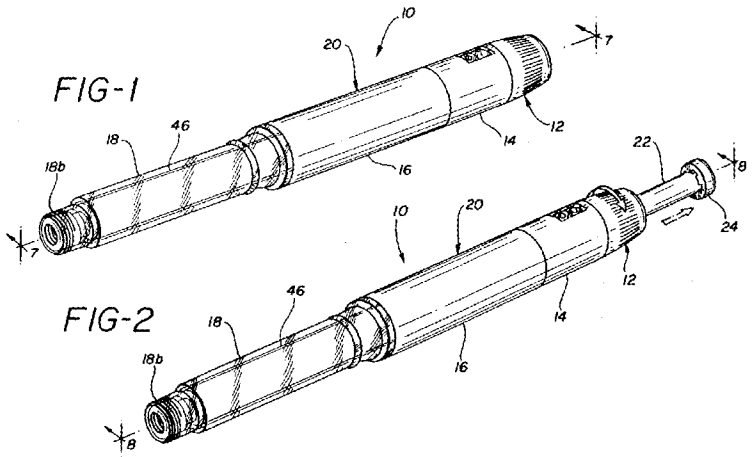
Fig. 10

The present invention, as is exemplarily embodied in Figures 1, 4 and 6-10, increments a dose application counter ***by a standard increment***, irrespective of the extent of movement of the dose setting element beyond a minimum dose application. The dose application counter keeps a tally of the number of doses that have been set, and is entirely independent of the dosage volume that has been delivered. In other words, if user is uncertain as to whether they have taken a dose that day, they can look at the day showing on the dose application counter to confirm whether the dose for a particular day has been taken.

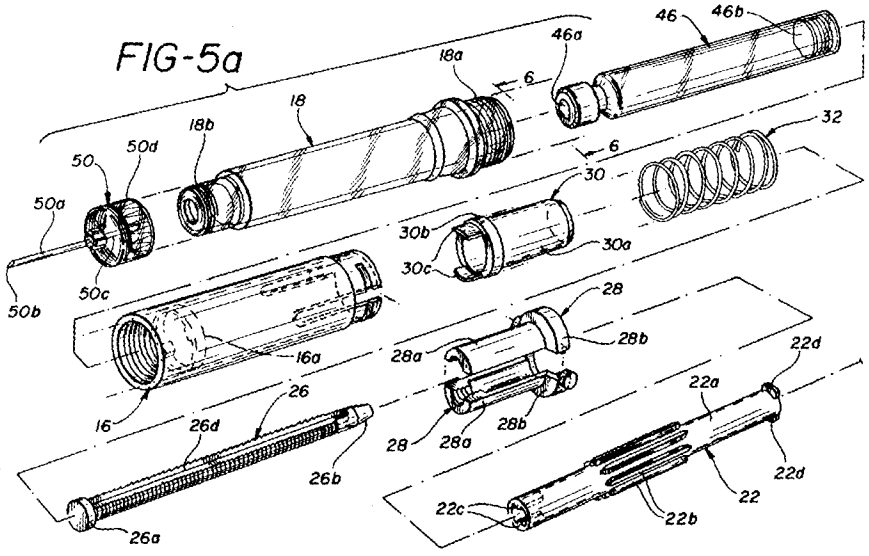
Also the feature in the final part of the present invention's claim 15 that return of the dose setting element to its initial position is not effective to more than counter member means that in those devices where the dose setting element

returns to its initial position, the count of the dose application counter is not lost or decremented by such movement.

BALKWILL pertains to a medical delivery pen. Figures 1 and 2 of BALKWILL are reproduced below.



An exploded view of the medical pen of BALKWILL is shown in Figure 5a, which is reproduced below.



Specifically, BALKWILL discloses an arrangement in which the user dials in a dose using a dose setting element 12.

Turning the dose setting element rotates a “units” counter wheel 36 to indicate the extent of movement and thus the volumetric dose that will be applied when the plunger button 24 is pressed. The “units” counter wheel trips a “tens” counter wheel 38 when it reaches 9 on the wheel. The counter wheels 36, 38 measure the volume of the dose but do not count the number of dose applications, nor can they because at each operation the first step required of the user is to ***return the counter to zero*** (see col. 5, lines 1 and 2). Upon zeroing the counter the plunger 22 is released to move rearwardly to extend from the rear end of the device (col. 5, lines 14-18). The dose is then set by rotating the dose setting knob which turns a lead screw 26 which advances by an amount dependent on the angular extent of rotation approved. (col. 5, lines 29-31). The injection is then made by pushing in a push button 24 on the end of the plunger, which pushes forward the syringe piston by an amount corresponding to the dose set.

BALKWILL does not therefore disclose a dose application counter. It does not have a counter member connected by a lost motion connection to the dose setting element. The Official Action asserts the counter member 36 as being covered by a lost motion connection 44 to the dose setting element 12. In fact, as described in Col. 7, line 64 to Col. 4 line 3, “*the counter ring 36 is also secured to the adjusting knob 12 such that rotation of*

the knob ***causes a corresponding motion*** *of the counter ring*" and so there is no lost motion here.

Furthermore, movement of the dose setting element 24 by and beyond an amount to set an effective dose does ***not*** cause an incremental movement of the counter member 36; instead the counter member 36 simply moves with the dose setting element in non-incremental fashion. Finally, return of the dose setting element to its initial position zeroes the counter. Balkwill does not provide an arrangement in which "*return of said dose setting element to said initial position is not effective to move said counter member.*" Instead, it clearly does move the counter member.

BALKWILL thus does not teach each and every element of claim 15 of the present invention. BALKWILL accordingly does not anticipate claim 15 of the present invention. Claims depending upon claim 15 are patentable for at least the above reasons.

This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

Conclusion

In view of the present amendment and the foregoing remarks, it is believed that the present application has been placed in condition for allowance, and reconsideration and allowance are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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